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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,960	05/29/2001	Neil D. Scancarella	Rev 01-6	7403

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/866,960	Applicant(s) SCANCARELLA ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and request for extension of time filed 08/09/07. Claim 1 is amended. Claims 1-20 are pending.

Claim Amendment/Listing of claims.

The listing of claims filed 08/09/07 does not comply with the Manner of Making Amendment under 37 CFR 1.121 which requires that all amendments filed on or after July 30, 2003 must comply with 37 CFR 1-121. In the present amendment filed 08/09/07, a complete listing of all claims is not provided with the appropriate status identifiers --- claims 21-87 were canceled 5/23/07, but are required to be listed with the appropriate status identifiers in order to comply with 37 CFR 1.121.

It is suggested that applicant provide claim listings that is compliance with the manner of making amendment under 37 CFR 1.121.

New Matter Rejections

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejections.

Amended claim 1 requires that the emulsion composition contain a “combination of at least two organic pigments.” The specification as filed describes that at least one organic pigment can be present in the composition (see original claims 1, 30, 48, 66, 91 and 86; abstract; paragraphs [0012] to [0016]. At least one requires a minimum of one organic pigment and at least two requires a minimum of two. There is no support for this in the as filed specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-20 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Patil et al. (US 6,342,209).

The amended generic 1 claims is drawn to water and oil emulsion (e.g., water in oil emulsion or oil in water emulsion) which comprises silicone resin film forming polymer; at least one film forming polymer selected from the group consisting of (i) a silicone/acrylate copolymer, (ii) a vinyl/silicone copolymer or a mixture thereof; at least two organic pigments that are not black or brown, that when combined achieve a deep brown or black color and such pigments are free from iron oxides.

Patil teaches a cosmetic composition such as a mascara product is made into the form of water-in-oil or oil-in-water emulsion, wherein the mascara contains 0.1-50% water, 0.5-

Art Unit: 1618

55% oil, 0.1-30% pigment and 0.1-30% of one or more synthetic polymers (e.g., film forming polymers) see col. 12, lines 37-44. In light of Patil's teaching in his disclosure, one or more film forming polymers (synthetic polymers) are present in the composition at from 0.1-95% and the one or more film forming polymers are selected from silicone resins (e.g., trimethylsiloxysilicate), silicone/acrylate copolymers and so on, see col. 2, lines 62-col. 3, lines 41. US'209 teaches organic pigments to be present at about 0.1-30%, see col. 8, lines 10-29. Furthermore, US'209 teaches silicone oils including volatile cyclic silicone oils (e.g., cyclomethicone present at about 0.5-95%, see col. 6, lines 50-67), and an oil phase comprising dimethicone and isohexadecane or isododecane, (see col.7, lines 26-43); and **0.1-50%** water.

As to claims 4-13, all the critical elements required by the instant claims are well taught at col. 8, lines 9-29. For example, US'209 teaches azo, triphenylmethane, anthraquinone, xanthene dyes which are designated as D&C and FD&C blues, browns, greens, oranges, reds, yellows, etc dyes.

It is noted that the recitation found in preamble of claim 7 has not been given patentable weight. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, structural limitations are able to stand-alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is note that claim 15, which requires Dimethicone having viscosity of 1 centipoise at 20°C, which is met by the cited reference because Patil teaches dimethicone and a viscosity of 1 centipoise at 20°C is inherent property and thus the claim is met. Thus, one skilled artisan readily envisaged the claimed invention from Patil's teaching.

Even if the claimed composition has not been duplicated in any examples, exemplified composition and minor variations in order to maximize industrial applicability as well as customer satisfaction is modified in routine practice. As to Claims 9 and 14, for example, claim 9 requires monoazo whereas US'209 teaches azo; claim 14 requires pyrazole as yellow pigment whereas US'209 teaches other yellow pigments, said modification are already well known in the art at that time of the invention was filed and does not render the claims patentable (see evidentiary documents, PTO-892, US6458390, 6326013, 6091491). Therefore, even if applicant argues that Patil's reference is not anticipating the claimed invention because it has not been identically exemplified, the claimed invention is readily apparent and considered to be obvious over the teaching of Patil's patent and prior art of the record.

Each critical element required by the instant claims is taught by cited reference and minor variations such as selection of active agents and carriers including the selection of its derivatives and analogs (functionally equivalent species), mixing and adjusting process in order to determine most effective outcome (results) is considered to be well within the skilled level of the artisan.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan and thus, obvious, absent evidence to the contrary. Thus, the claimed subject matter is well within the scope of the patented invention, which renders the claims not patentably distinct over the prior art of the record.

Art Unit: 1618

All the critical elements are well taught by the cited reference and the claimed invention is properly included in this rejection.

Response to Arguments

5. Applicant's arguments filed 08/09/07 have been fully considered but they are not persuasive.

Applicant argues

- (i) That Patil does not disclose combining at least two organic pigments that are not black or brown in color, which when combined produce deep brown or black color and where said pigments are free from iron oxide and therefore, the scope and content of Patil is different from that "disclosed in the subject application;"
- (ii) That Patil does not disclose the use of specific pigments in combination to achieve a black or dark brown color and applicant refers to column 5, line 63 to column 6, line 1 of Patil; and
- (iii) That Patil teaches against the subject invention by "suggesting" the use of iron oxides as suitable pigment at column 5, lines 66 and 67.

Response:

Regarding (i), the production of deep brown or black color from the combination of at least two organic pigments is an inherent property resulting from the combination of the organic colors. It is also noted that in claim 1, no specific colors are indicated that, which, when combined would produce the black or deep brown color. Further, Patil discloses the use of one or more organic pigments (column 5, lines 44, 65-67). While column 5, lines 65-67 state that the pigments that can be used include iron oxides, the FD&C and D&C colors and titanium oxide, the teaching indicates

Art Unit: 1618

that one or more of either of the pigments listed can be used and even mixtures; Patil does not explicitly or implicitly teach that iron oxide must be used with organic pigments. Regarding the argument that the scope and content of Patil differs from that “disclosed in the subject application,” it is noted that while the claims are interpreted in light of the specification, limitation from the specification is not read into the claims.

Regarding (ii), Patil as described above discloses the specific organic pigments, namely, azo, indigoid, triphenylmethane, anthraquinone, xanthene dyes which are designated as D&C and FD&C blues, browns, greens, oranges, reds, yellows, etc dyes (column 8, lines 12-17) which are some of the pigments recited in claims 5-14. “Combination to achieve a black or dark brown color” is a consequence of the combination of the colors and combining one or more of the organic pigments of Patil would also result in the production of the black and dark brown color.

Regarding (iii), Patil does not teach against the subject invention because a suggestion that iron oxide is a suitable pigment means that iron oxide can be used a pigment but that suggestion does not categorically say that iron oxide must be used in combination with the organic pigments.

No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1618

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

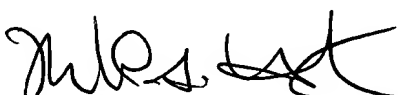
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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